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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,235	07/18/2000	Donn Nelson Rubingh	7670	8554

27752 7590 06/09/2004

THE PROCTER & GAMBLE COMPANY
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EXAMINER

MOORE, WILLIAM W

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/618,235	Applicant(s) RUBINGH ET AL.	
	Examiner William W. Moore	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Arguments

Applicant's Response filed May 5, 2004, to the communication mailed January 5, 2004, has been entered and Applicant's arguments filed May 5, 2004, have been fully considered but they are not persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are for reasons of record rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues at page 2 of the Response filed May 5, 2004, that the "content of the application disclosure" is the primary factor that might "define the [intended] subject matter with a reasonable degree of particularity and distinctness". But Applicant points to no passage in the specification that might tend to define the intended subject matter of an "addition moiety" of the claims, or that which is "not nil" in such a moiety, and Applicant points to no prior art teachings of record that might aid the artisan and the public seeking to determine the nature of the "addition moiety", or that which is "not nil", of the claims. Applicant declines to suggest how "one possessing the ordinary level of skill in the relevant art" might give a particular "claim interpretation" to that which is "not nil" in the "addition moiety" of the claims, thus claim 1, where the term "addition moiety" appears, and claim 2 where it is represented figuratively, remain indefinite in failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Where claim 2 depends from claim 1, their ambiguity is inherent in the descriptions of claims 3-21 depending therefrom where the "linking moiety", which is the "X" of the "addition moiety" of claim 2, has a bond extending to no particular molecule

and two further bonds extending to separate molecules "R₁" and "R₂". While a following clause indicates that "X" is either a "linking moiety" or "nil", and that either or both of the further, separate, molecules "R₁" and "R₂" may be one of a first, or second, polypeptide, a first, or a second, polymer, or "nil", so long as one of "X", "R₁", and "R₂" may be, as recited in the phrase "not nil", i.e., something, what the something is that permits an addition moiety to exist in the presence and absence of "X" is ambiguous. As noted in the communication mailed January 5, 2004, the final claim term, "not nil", is a double negative, "not nothing", because "nil" means "nothing" according to Webster's Ninth New Collegiate Dictionary (Merriam-Webster 1990).

Applicant does not argue that the terms "nil" and "not nil" in claim 2 be interpreted, respectively, as "absent" and "present", nor replace the claim terms by amendments substituting "absent" and "present". No claim is amended to positively recite the nature of a "something" that is an "X" and that contributes to a conjugate whether it is there or not. Should an X be present, it might extend, see claim 3, to a protease having an epitope protection position among the six subtilisin BPN'-correspondent positions of claim 1 that Applicant has elected so that the protease is part of the conjugate. But if X is nil, can there be a conjugate? Can "R₁" and/or "R₂" somehow both be linked to a single amino acid at an epitope protection position where "X" is "nil"? Yet if "X" is "not nil" and both of "R₁" and "R₂" are absent, does a protease conjugate exist that has a protected epitope position? Is it necessary, or merely permissible, that either of "R₁" and "R₂" be the protease part of the conjugate indicated by claims 3-18 or must the protease be present at the undesignated extension of the "X" that is not "R₁" or "R₂"? If some part of the specification supports an amendment making the meaning of the figure embedded in claim 2, together with recitations that accompany it, reasonably distinct and particular, it is not apparent and Applicant does not point to it.

Applicant also declines to separately address additional aspects of the rejection of record whereby claims 1-21 were rejected as further indefinite because claims 2-19, the limitations of which must be incorporated in claims 1, 20 and 21, all attempt to make a distinction between, claim 2, a "first polymer" and a "first polypeptide", or between a "second polymer and a "second polypeptide" where such distinction is not possible because a polypeptide is a polymer of amino acids. Neither the specification nor the claims make a distinction between heteropolymers and homopolymers, thus an amendment to claims 2, 14, 15, and 19 that substitutes the term "non-peptide polymer" for "polymer" would address this aspect of the rejection. Applicant declines to amend these claims or to amend claim 9 which was independently rejected as indefinite because, no matter what "X" might be, a "protease conjugate" of claims 1 and 8 from which claim 9 ultimately depends does not appear to have anything conjugated to it where both "R₁" and "R₂" are "nil". Applicant declines to clarify the claims by (1) describing the **presence or absence** of either of the separate molecules "R₁" and "R₂" in a linking moiety and (2) by defining "X" either as a linking "molecule", see pages 12-14 of the specification, or as a covalent bond, thus resolving the issue of its absence.

Applicant also fails to address other issues raised in the rejection of record: Claim 6 remains independently indefinite where no limitation in the chain of dependency linking it to claim 1 distinguishes its subject matter from that of claim 1. Claim 11 remains independently indefinite where it fails to definitely describe a first polypeptide as a protease distinct from the original protease in a conjugate claims 1 and 6, thus may be construed to describe an intramolecular conjugate of at least two proteases, a result not discussed in the specification, thus not clearly intended by the claim. Claim 12 remains independently indefinite because it fails to describe how the positions recited are to be identified among the six native proteases and four altered proteases of claim 11.

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Conclusion

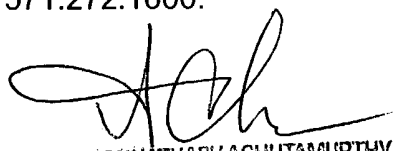
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
June 2, 2004



PONNATHAPU ACHUTAMURTHY
SUPERVISOR, PATENT EXAMINER
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